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APPLICATION NO	. ]	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/721,388 11/25/2003		11/25/2003	Robert Joseph Panek JR.	TC01-101US2 8046	
23122	7590	12/19/2005		EXAMINER	
RATNER	PRESTIA		LUONG, SHIAN TINH NHAN		
POBOX 9		PA 19482-0980	ART UNIT	PAPER NUMBER	
VILLEDI	onoz, i	11 19 102 0900	3728		
			DATE MAILED: 12/19/2005		

Please find below and/or attached an Office communication concerning this application or proceeding.

<del></del>		Applicat	on No.	Applicant(s)						
		10/721,3	88	PANEK ET AL.						
Office Action Summary			r	Art Unit						
		Shian T.	_uong	3728						
	The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply									
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).  Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).										
Status										
1)	Responsive to communication(s) filed	on								
2a) <u></u> □	This action is FINAL. 2b)⊠ This action is non-final.									
3)										
	closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.									
Disposition of Claims										
4)🛛	Claim(s) 1-15 is/are pending in the app	olication.								
•	4a) Of the above claim(s) is/are withdrawn from consideration.									
5)	5) Claim(s) is/are allowed.									
•	6)⊠ Claim(s) <u>1-15</u> is/are rejected.									
•	7) Claim(s) is/are objected to.									
8)[	8) Claim(s) are subject to restriction and/or election requirement.									
Applicati	on Papers									
9)[	The specification is objected to by the E	Examiner.								
10)	The drawing(s) filed on is/are: a	i) accepted or b	$\square$ objected to by the f	Examiner.						
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).										
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).										
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.										
Priority u	ınder 35 U.S.C. § 119	•								
12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of:										
	1. Certified copies of the priority documents have been received.									
	2. Certified copies of the priority documents have been received in Application No									
	3. Copies of the certified copies of the priority documents have been received in this National Stage									
application from the International Bureau (PCT Rule 17.2(a)).										
* See the attached detailed Office action for a list of the certified copies not received.										
Attachment			4) Interview Summary	(DTO 413)						
	e of References Cited (PTO-892) e of Draftsperson's Patent Drawing Review (PTC	)-948)	Paper No(s)/Mail Da	ate						
3) 🔯 Inform	nation Disclosure Statement(s) (PTO-1449 or PT · No(s)/Mail Date <u>11/25/03</u> .		5) Notice of Informal P 6) Other:	atent Application (PTC	D-152)					

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# Double Patenting

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 1-4,6-14 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4,7-13 of U.S. Patent No. 6,712,207. Although

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the conflicting claims are not identical, they are not patentably distinct from each other because the first and second configurations defined in the patented claim include the shape of the adapter aperture and the lid aperture.

### Claim Rejections - 35 USC § 112

- 3. The following is a quotation of the first paragraph of 35 U.S.C. 112:
  - The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
- 4. Claims 1 and 12 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification. The claims contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This includes converging wall portions in the lid aperture or the adapter aperture positioned to contact a release mechanism of the needle holder of the respective needle system to expand an opening defined in the needle holder to release the needle portion from the need holder. Clarification is required.
- 5. Claims 1 and 12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claims 1 and 12, the specification does not provide written description on converging wall portions in the lid aperture or the adapter aperture positioned to contact a release mechanism of the needle holder of the respective needle system to expand an opening defined in the needle holder to release the needle portion from the need holder

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### Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.
- 7. Claim 15 is rejected under 35 U.S.C. 102(b) as being anticipated by Thead et al. (US 6,158,314). Thead et al. disclose a receptacle 20 with an opening. A lid 58 is configured to cover said receptacle opening, said lid defining an aperture having a shape as shown in Figure 5. An adapter 26 configured for engagement in the lid aperture. The adapter having an aperture with a different configuration with respect to the one aperture on the lid. At least one flange is shown in Figures 4a and 4b that extends below the first aperture. The lid aperture has converging wall portions (the flat surface adjacent to the aperture) to contact the needle holder and the adapter aperture has converging wall portions 54 to contact the needle holder. The element 54 is divided into two wall portions.
- 8. Claims 1,12-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Segstetter et al. Sagstetter et al. discloses a receptacle 10 with an opening. A lid is configured to cover said receptacle opening, said lid defining an aperture having a rectangular shape above converging wall portions. An adapter 230 is configured for engagement in the lid aperture. The adapter having an aperture with a different configuration with respect to the aperture on the lid. The aperture has converging wall portions to contact a needle holder.

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9. Claim 15 is rejected under 35 U.S.C. 102(b) as being anticipated by Pepper (US 4,488,643). Pepper discloses a receptacle 10 with an opening. A lid is configured to cover said receptacle opening, said lid defining an aperture having a shape. An adapter 56 is configured for engagement in the lid aperture. The elements 62,65,66 are the engagement elements for engaging the grooves.

## Claim Rejections - 35 USC § 103

- 10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
  - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 11. Claims 1, 3-5,9-10,12-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Thead et al. of Thead et al in view of Official Notice. Although the shape of the aperture in the lid is not a funnel shape and the shape of the adapter is not rectangular, it would have been obvious to provide any desired shape for the lid opening and adapter opening as long as it engages the shape of the intended article. A change in form or shape is generally recognized as being within the level of ordinary skill in the art, absent any showing of unexpected results. *In re Dailey et al.*, 149 USPQ 47.

Alternatively, it is well known in the art to provide the corresponding shape to receive the shape of the intended article. It would have been obvious to provide any desired shape for the lid opening and adapter opening as long as it engages the shape of the intended article

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12. Claims 1,3-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sagstetter et al.. Although the shape of the aperture in the lid is not a funnel shape and the shape of the adapter is not rectangular, it would have been obvious to provide any desired shape for the lid opening and adapter opening as long as it engages the shape of the intended article. A change in form or shape is generally recognized as being within the level of ordinary skill in the art, absent any showing of unexpected results. *In re Dailey et al.*, 149 USPQ 47.

Alternatively, it is well known in the art to provide the corresponding shape to receive the shape of the intended article. It would have been obvious to provide any desired shape for the lid opening and adapter opening as long as it engages the shape of the intended article

Claims 1-6, 9-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pepper. Pepper discloses a receptacle 10 with an opening. A lid is configured to cover said receptacle opening, said lid defining an aperture having a shape. An adapter 56 is configured for engagement in the lid aperture. The elements 62,65,66 are the engagement elements for engaging the grooves. However, the elements are considered the flange section with respect to claims 9-11. The adapter having an aperture with a different configuration with respect to the aperture on the lid. The depression is located adjacent to element 60.

Although the shape of the aperture in the lid is not a funnel shape and the shape of the adapter is not rectangular, it would have been obvious to provide any desired shape for the lid opening and adapter opening as long as it engages the shape of the intended article. A change in form or shape is generally recognized as being within the level of ordinary skill in the art, absent any showing of unexpected results. *In re Dailey et al.*, 149 USPQ 47.

Alternatively, it is well known in the art to provide the corresponding shape to receive the

shape of the intended article. It would have been obvious to provide any desired shape for the lid opening and adapter opening as long as it engages the shape of the intended article

#### Allowable Subject Matter

14. Claims 7-8 would be allowable if rewritten to overcome the rejection(s) under 35
U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims. The claims also have to overcome the double patenting rejection.

#### Conclusion

15. Telephone inquiries regarding the status of applications or other general questions, by persons entitled to the information, should be directed to the group clerical personnel and not to the examiners. In as much as the official records and applications are located in the clerical section of the examining groups, the clerical personnel can readily provide status information without contacting the examiners, M.P.E.P. 203.08.

If in receiving this Office Action it is apparent to applicant that certain documents are missing, e.g., copies of references cited, form PTO-1449, form PTO-892, etc., requests for copies of such papers should be directed to Erica Miller at (571) 272-4370.

For applicant's convenience, the official FAX number is 571-273-8300. This practice may be used for filing papers not requiring a fee. It may also be used for filing papers which require a fee by applicants who authorize charges to a PTO deposit account. Please identify

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Examiner <u>Luong</u> of Art Unit <u>3728</u> at the top of your cover sheet of any correspondence submitted.

Inquiries concerning the merits of the examination should be directed to Shian Luong whose telephone number is (571) 272-4557. The examiner can normally be reached on M-H from 7:00am to 4:00pm EST.

STL December 11, 2005

Primary Examiner Shian Luong Art Unit 3728